K060661

APR 7 2006

Section 2 Summary

510(k) Summary of Safety and Effectiveness

Date: March 10, 2006

Submitter: GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Karen Russell
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: 414-362-3166
Fax: 414-362-2585

Device: Trade Name: Mactrode® 3

Common/Usual Name: Electrocardiograph electrode

Classification Names:
21 CFR 870.2360 Electrocardiograph Electrode DRX

Predicate Device: K902176 Silver Mactrode®

Device Description: The Mactrode® 3 is an electrocardiograph electrode. The Mactrode® 3 is triangular in shape providing multiple alternate connection areas. The Mactrode® 3 is a pre-gelled electrode that is disposable and is not sterile.

Intended Use: The Mactrode® 3 is intended for use on adult patients during an ECG electrocardiogram test. The Mactrode® 3 is applied to the patient's skin. The Mactrode® 3 is intended to be used for less than one hour. The Mactrode® 3 is for single patient use.

The Mactrode® 3 is intended to be used under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The Mactrode® 3 is intended for use in a professional medical facility, such as a hospital, clinic or doctor's office.

Technology: The Mactrode® 3 employs the same functional technology as the predicate device.

Test Summary: The Mactrode® 3 complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Technical Reviews
- Design Reviews
- Unit level Testing
- Performance Testing
- Safety Testing

Conclusion: The results of these measurements demonstrated that the Mactrode® 3 is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

GE Medical Systems *Information Technologies*
c/o Karen Russell
Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K060661
Trade Name: Mactrode® 3
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: March 10, 2006
Received: March 13, 2006

Dear Ms. Russell:

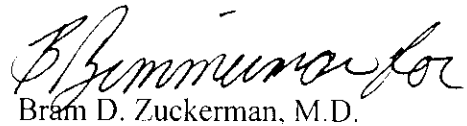
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K060661

Device Name: Mactrode® 3

Indications For Use:

The Mactrode® 3 is intended for use on adult patients during an ECG electrocardiogram test. The Mactrode® 3 is applied to the patient's skin. The Mactrode® 3 is intended to be used for less than one hour. The Mactrode® 3 is for single patient use.

The Mactrode® 3 is intended to be used under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The Mactrode® 3 is intended for use in a professional medical facility, such as a hospital, clinic or doctor's office.

Prescription Use_X_ (Per 21 CFR 801.109 Subpart D) OR Over-The-Counter Use____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060661